Efficacy of paracetamol and diclofenac for patients with acute low back pain: a randomized placebo controlled trial (PACE plus trial)

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Based on the identified gaps in the evidence underlying the clinical guidelines on non-specific low back pain of the Dutch College of GPs and the recent findings of the Australian PACE study the objectives of the present study are: 1. What is the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44078

Source
ToetsingOnline

Brief title
PACE plus trial

Condition

- Other condition
- Joint disorders

Synonym
acute low back pain; pain medication

Health condition

pijn

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: diclofenac, low back pain, paracetamol, placebo

Outcome measures

Primary outcome

The primary outcome will be pain intensity (11-points numerical rating scale).

This will be captured in a (digital) daily pain and medication use diary that

particpants will complete over a 4 week follow up period

Secondary outcome

Secondary outcomes:

1. Disability measured at baseline and after 2, 4 and 12 weeks of follow up

using the Roland Morris Disability Questionnaire (score range 0-24; higher

score means more disability);

2. Patients* perceived recovery measured after 2, 4 and 12 weeks of follow-up

using a 7-point Likert scale; scores will be dichotomized into recovered or not

recovered;

3. Quality of life measured at baseline and after 4 and 12 weeks of follow-up

using the EQ-5D-5L;

4. Costs; all direct medical and patient costs measured after 4 and 12 weeks of

follow-up using the iMedical Consumption Questionnaire (iMCQ), and productivity

costs measured with iProductivity Cost Questionnaire (iPCQ);

5. Time to recovery will be assessed using the daily pain diary. Recovery is defined as the first day of 0 or 1 pain intensity, maintained for 7 consecutive days;

6. Compliance to treatment measured daily using a digital diary. The question that will be used is derived from the Brief Medication Questionnaire;

7. Adverse reactions, systematically recorded in the questionnaires after 2, 4 and 12 weeks of follow-up;

8. Patient satisfaction measured after 2, 4 and 12 weeks of follow-up using an 11-point numerical rating scale; higher score means more satisfaction;

9. Sleep quality measured at baseline and after 2, 4 and 12 weeks of follow-up using a 4 point Likert scale derived from the Pittsburgh Sleep Quality Index (PSQI); scores will be dichotomized into good sleep quality and poor sleep quality;

10. Co-interventions will systematically be recorded in the questionnaires after 2, 4 and 12 weeks of follow-up.

All secondary outcomes will be recorded using digital questionnaires.

Study description

Background summary

Low back pain is a common diagnosis that is associated with a considerable burden to patients and society. The clinical guideline on non-specific low back pain of the Dutch College of GPs advises paracetamol as first option and NSAIDs as second option for prescribing analgesics for patients with acute non-specific low back pain. In 2014, the first randomized placebo-controlled trial (RCT) of paracetamol for acute non-specific low back pain was published (PACE study). They showed that paracetamol was not more effective than placebo

in patients with acute low back pain.

Study objective

Based on the identified gaps in the evidence underlying the clinical guidelines on non-specific low back pain of the Dutch College of GPs and the recent findings of the Australian PACE study the objectives of the present study are:

1. What is the effectiveness of paracetamol versus placebo regarding pain intensity over 4 weeks in patients with acute low back pain in general practice?
2. What is the effectiveness of diclofenac versus placebo regarding pain intensity over 4 weeks in patients with acute low back pain in general practice?
3. What is the effectiveness of paracetamol versus diclofenac regarding pain intensity over 4 weeks in patients with acute low back pain in general practice?

Study design

Patients who fulfill the in- and exclusion criteria and who either visit their GP or call the doctor's assistant on the phone because of acute low back pain, will be informed about the trial by the GP or by the doctor's assistant, respectively. If patients are interested in participation in the trial (and in the case of recruitment over the phone by a doctor's assistant, if a GP has given consent for participation of this patient), the patient's contact details will be sent to the research institute. Written information and informed consent form will be given or sent to the patients. Patients will be contacted within 24 hours by a researcher. Eligibility will be checked, there will be room for questions and consequently, the written informed-consent forms will be signed by the patient and send to the research institute both digitally (using either e-mail or fax) and through the mail. After receiving the digital signed informed consent form, the digital baseline assessment will be completed by the patient. Patients will consequently be randomized, using a randomization schedule, based on a random number generator and prepared by an independent datamanager not involved in the study. The GP and pharmacist of the patient will be informed about the participation of the patient in the PACE Plus trial. Blinded trial medication will be allocated, prepared and numbered by an independent pharmacy, not involved in the recruitment or follow-up of the patients. Medication will be sent to the patient in the mail. Patients may use prescribed and/or over-the-counter pain medication as usual until the study medication arrives.

Intervention

Study treatments:
Group 1: Paracetamol 4dd1000 mg + placebo diclofenac 2dd
Group 2: Diclofenac 2dd75 mg + placebo paracetamol 4dd

Group 3: Placebo paracetamol 4dd + placebo diclofenac 2dd
Since the dosage schemes of NSAID and paracetamol differ we will make use of double dummies (i.e. placebo paracetamol and placebo diclofenac) in order to optimally blind patients, physicians and outcome assessment.

Study burden and risks

The burden for the patients will be minimal because the trial will evaluate medications that are already prescribed frequently in patients with low back pain. Besides that, the allocated medication will be prescribed conform the clinical guidelines of the Dutch College of GPs. A rather small burden for the patients is that they have to fill in 4 digital questionnaires in a period of 3 months, and assess their daily pain and compliance to prescribed medication (when applicable) in a digital diary during 4 weeks. Patients allocated to medication may experience side effects from these medicaments.

Contacts

Public
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Mentally competent patients (male and female) presenting in general practice with acute non-specific low back pain;
- Between 18 and 60 years old;
- Experiencing a new episode of low back pain, preceded by a period of at least one month without low back pain;
- Duration of pain less than 6 weeks (in accordance with the Cochrane Collaboration Back Review Group definition for 'acute' pain;
- Primary complaint of pain in the area between the 12th rib and buttock crease, with or without leg pain;
- Low back pain severe enough to cause at least moderate pain (* 4 on 0-10 Numerical Rating Scale (NRS);
- Signed consent form.

Exclusion criteria

- Known or suspected serious spinal pathology (e.g. metastatic, inflammatory or infective diseases of the spine, cauda equina syndrome, spinal fracture);
- Currently taking recommended regular doses of analgesics conforming with the study protocol (e.g. paracetamol 4dd1000mg, diclofenac 2dd75mg or 3dd50mg);
- Spinal surgery within the preceding 6 months;
- Serious co-morbidities such as rheumatoid arthritis, heart failure, diabetes, renal insufficiency, gastric ulcers, gastro-intestinal pathology, allergy for paracetamol and/or NSAIDs or other indications preventing prescription of paracetamol and/or NSAIDs; use of proton pump inhibitors before inclusion is not an exclusion criterium, as the patient is considered to be protected (patient will have to continue using this medication during use of study medication);
- Use of coumarin derivatives, clopidogrel, prasugrel, ticagrelor, acetylsalicylic acid derivatives, systemic glucocorticosteroids, SSRIs, venlafaxine, duloxetine, trazodone, spironolactone or other medication that may interact with paracetamol and/or diclofenac;
- Known intolerance for paracetamol and/or diclofenac;
- Patients who are pregnant or planning to become pregnant during the treatment period.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2016
Enrollment:	600
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	diclofenac
Generic name:	diclofenac
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	paracetamol
Generic name:	paracetamol
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	12-02-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	13-07-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-08-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-10-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-12-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-01-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-01-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-02-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2015-003882-26-NL
CCMO	NL54941.078.16